IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Alan M. ZAMORE

Art Unit: 1773

Application No: 10/688,292

Examiner: JACKSON, Monique R.

Confirmation No: 6496

For: REDUCED PROFILE MEDICAL BALLOON ELEMENT

Filing Date: October 17, 2003

Declaration of Alan Zamore under 37 C.F.R. § 1.132

Mail Stop Amendment
Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, the undersigned, declare the following, based on my own knowledge, information, and belief.

1. I am the inventor of the subject matter described and claimed in the above-identified U.S. Patent Application. I have worked in the field of medical devices in excess of 12 years. During that period I have applied my knowledge of polymeric material properties towards improvements and innovations with respect to catheters, angioplasty balloons and cardiac pacing leads. I am an inventor holding four U.S. patents, three pending US patent applications including the present application, and several issued foreign patents. I have received several NIH SBIR research grants in the field of medical devices including angioplasty balloon catheters and cardiac pacing leads. I possess a BA degree with a major in chemistry, and have attended post graduate studies in the fields of Biochemistry and Medicine.

2. My innovation, "an axially restrained shrunk catheter balloon", is made as described in paragraphs 81 through 87 of this application, and shown in Figure 1. The innovation, as recited in paragraph 83 line 4, involves processing a formed balloon, by applying heat, so that the balloon shrinks primarily in the radial direction.

3. When using existing methods for forming a balloon from a tube, the tube is stretched both axially and radially (paragraph 32 lines 5-11) . This imparts shrink "memory" to the balloon both axially and radially. Therefore, when such a balloon is heated in an unrestrained manner, the "shrink memory" will be expressed so that the formed balloon will shrink both axially and radially. That is, it will get smaller in diameter and shorter.

4. However, if as recited in this application, for example in paragraph 84, my innovative restraining step is applied, the balloon will be prevented from shrinking axially (that is it will be prevented from becoming shorter) during the application of heat and will only shrink radially. This restraining step involves holding the ends of the balloon in a fixed position (in one embodiment) so they cannot contract during the heat shrinkage step. At the end of the application of heat the balloon is cooled and a new radially smaller balloon will be obtained with the axial dimension (length) remaining as it was prior to the application of heat. Thus, a balloon is obtained which is narrower than the original balloon but retains the axial length of the original unshrunk balloon. The advantage of such a balloon is that it will re-expand radially upon the application of internal pressure without exhibiting a highly undesirable lengthening in the axial direction. Also, the walls in the shrunken balloon will be thinner than walls of balloons allowed to shrink axially.

5. Without the axial restraint, axial growth occurs on re-inflation of such a shrunk balloon and is undesirable. When re-inflated during use, such a balloon exhibiting axial growth, will expand to a less certain length, potentially exposing healthy arterial tissue outside the stenosis to be treated to unwanted balloon pressure. This can result in scarring and re-closing (restenosis) of the treated arterial lumen. It also can cause a deformation of the catheter beyond its elastic limit resulting in difficulties with re-inflation or deflation or withdrawal of the catheter during or after the dilation of the stenosis.

6. In order to insert the catheter with a balloon into a vessel, the deflated balloon must be configured to a reduced diameter so that it does not extend significantly beyond the outer catheter diameter. Current methods to reduce this profile involve folding and wrapping a full sized balloon about itself, often requiring that the folds overlap one another. Balloons prepared by prior methods exhibit a disadvantageous thickening and stiffening of the catheter in the balloon region when wrapped. Other methods for reducing the profile, such as in balloons attributed to Wang (7,108,826), use a shrunken balloon, but neglect to disclose axial

restraint during shrinkage. If one skilled in the art were to follow such a process, a balloon would be obtained which would be undesirably shrunken both axially and radially. Such a balloon is thicker and less flexible than the instant innovation. In addition it would exhibit the undesirable feature of axial growth during inflation. Axial growth during inflation has the potentiality for creating additional arterial damage during balloon deployment, as described above.

7. In contrast, the innovation of this application exhibits multiple advantages. For example, by axially restraining during shrinkage, the balloon can be shrunken to an extent where the requirement for folds in balloons which are less than about 2 mm OD can be eliminated. In balloons greater than 2 mm, the thickness of the catheter profile when folding is required can be reduced, compared to prior art balloons, because the shrunken size of the balloon allows the balloon can be folded in a manner where the folds do not overlap. When wrapping is required, the lack of overlapping folds provide a balloon that is more flexible and of lower profile than in balloons prepared by prior methods. Also, as described above, there are several advantages associated with decreased axial elongation during inflation.

8. In summary, use of my innovation translates into a balloon which has a lower profile, is more flexible and has greater penetration potential and deliverability than a balloon of the same inflated size produced by any other known method in the art of which I am aware.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed this 30 day of January, 2008

Alan Zamore, President
Zylon Corporation